SIEMENS

CUSTOMER SAFETY ADVISORY NOTIFICATION

To users of the V5Ms transesophageal transducer #32800000-#42300000

Dear Valued Customer:

This letter is to notify you of an issue with the V5Ms transesophageal transducer.

When does this issue arise and what is the potential risk?

We have received recent reports about the deterioration of material covering the articulating section of the V5Ms transesophageal transducer. Although to date, no patient injury has been reported, a compromise or fault in this material combined with a failure to use a probe cover as directed in the user manual may cause esophageal cuts, bleeding, and perforation to the patient, and severe trauma, electrical burns, and serious electrical hazards to the patient and the user.

However, a leakage current test can indicate cracks, cuts, tears, perforations, and protrusions in the articulation material. The potential risk is avoided only if you perform the recommended leakage current test of the transesophageal transducer prior to each use.

What steps can the user take to avoid potential risk of this issue?

To avoid the potential risk associated with this issue, the following steps are required:

- Perform the leakage current test for a transesophageal transducer prior to each use. Follow the manufacturer's instructions included with the tester.
- Use only Siemens approved cleaning and disinfecting solutions. Carefully follow the manufacturer's instructions.
- Siemens recommends that you use market-cleared transducer sheaths specifically designed for TEE applications. Follow the instructions provided by the manufacturer of the transducer sheath.
- When you store the transesophageal transducer, take extreme care that the distal tip is straight. Never move the distal tip by hand. Always use the flex controls.

The recommended steps are provided in the existing user manual for your ultrasound system.

How will this issue be resolved?

If you notice any damage or wear on your transducer, or if the transducer fails to pass the leakage current test, immediately discontinue use of the transducer and contact your local Customer Service Engineer. If you have any questions, please contact your local service support person for information regarding timelines and status.

Please share this information with all personnel within your organization who need to be aware of this issue.

As always, patient safety issues are a high priority, and we alert customers of product concerns which may occur under various conditions. This problem was discovered as part of our ongoing quality process.

We sincerely regret any inconvenience this condition may cause in your daily operations.

Sincerely,

Sheila Pickering, Ph.D.
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